

REMARKS

The Examiner's Office Action has been reviewed.

In response to the Examiner's objection to the drawings, submitted herewith for the Examiner's approval are annotated corrected drawing and replacement sheet for Figure 1.

In response to the Examiner's objection to the Abstract, a new abstract is submitted herewith for the Examiner's approval.

The Examiner has rejected Claims 2, 3, and 5 under 35 U.S.C. § 103(a) as being unpatentable over Hickle et al. (US 5,676,133) in view of Wright (US 2,222,971). Independent Claim 2, and dependent Claims 3 and 5, claim as an element "a face mask **having** **an inflow flapper valve**". Applicant has amended his Claim 2 to include the limitation of an "ambient-to-inside-the-mask inflow flapper valve with the flapper valve being located on the wall of the mask". Neither Wright nor Hickle teaches a mask having an-ambient-to-inside-the-mask flapper valve. Such a limitation places the present invention outside the teachings, and, in fact, contrary to the teachings of Wright and Hickle. Wright does teach a flapper valve but that teaching is one of a flapper valve that directs the gases inside of the mask to the outside of the mask. Such teaching is contrary to the teaching of the present invention.

The present invention's specification teaches "The intake hole has an associated flapper valve 42, to permit the passage of

a gas into the mask from the surrounding atmosphere and to prevent the gas from within the mask moving into the surrounding atmosphere" (Page 13, lines 1-6). Hickle teaches a one-way pressure relief valve (See Figure 16, #244) that is contained within the "manifold" and not contained within the wall of the mask. The present invention takes the complicated, difficult design of Hickle and improves it so that it is uncomplicated, inexpensive and more efficient. The Hickle patent teaches a relief valve that is remote from the patient's mask and airway, and hence, the patient must generate a greater negative pressure to actuate the valve. In the present invention the valve is very close to the patient's airway. Any negative pressure generated is immediately felt by the valve, with the valve then opening and allowing ambient air to enter the mask. Because Hickle's valve is remote, the negative pressure must be generated within the mask and all along the length of the tubing, into the manifold of the device and, finally, then to the valve. By teaching a manifold mounted relief valve, Hickle teaches away from the concept of the mask relief valve, as is taught in the present application.

Applicant also points out that neither Hickle nor Wright teaches the use of a capnograph in conjunction with the mask. Such a teaching is not anticipated either implicitly or explicitly by Hickle or Wright.

Examiner has rejected Claims 2 and 4 under 35 U.S.C. §103(a) as being unpatentable over Hickle et al. (US 5,676,133) in view of Macris et al. (US 4,989,596).

Macris teaches a continuous positive pressure apparatus. The Hickle patent, however, teaches a system that has a pressure relief valve. "The third valve 248 is an inspiratory valve that opens upon the patient's inspirations and closes upon the patient's expirations to force his expirations to the vacuum circuit 231b" (Column 17, lines 37 - 40). Hickle anticipates and depends on the patient "pulling off" the pressure within the mask. It is the intent that such "pulling off" occur during use. Such a teaching is contrary to any continuous positive pressure breathing apparatus, as that which is taught by Macris. If a patient "pulls off" the positive pressure, any positive effects of such positive pressure are negated. Because the valve configuration of Hickle is contrary to the teachings of Macris, these two patents should not be combined to form the basis of an obviousness-type rejection. While Macris does teach a valve in the wall of the mask, the foundation of the teachings of Macris is that continuous positive pressure is to be applied to the patient's face area, and hence, to the patient's lungs. The present invention does not teach a positive pressure system. The present invention utilizes a gas scavenging system, meaning that the exhaust gases are collected and removed from the user.

Macris does not teach such a configuration. Macris also does not teach the use of a capnograph in conjunction with the use of the mask. Neither Macris nor Hickle teaches the use of a capnograph with their device.

Applicant submits that the preceding remarks, in conjunction with the amendments made to the Claims, places the application in condition of acceptance. The Applicant requests that the Examiner withdraw the rejections and objections, and pass the application forward to issue.

If the Examiner does not feel that this amendment places the application in condition for allowance, it is requested that the amendment be entered for purposes of appeal.

Respectfully submitted,



Edward P. Dutkiewicz
Reg. No. 46,676
640 Douglas Avenue
Dunedin, Florida 34698
(727) 734-2855
Fax (727) 734-2750



FIG 1

